

**NATURE OF CHARGE:** Adulteration, Section 402 (b) (2), a product containing less than 8.37 percent of salt-free tomato solids had been substituted for tomato puree.

Misbranding, Section 403 (g) (1), the article failed to conform to the definition and standard of identity for tomato puree since it contained less than 8.37 percent of salt-free tomato solids.

**DISPOSITION:** Charles Chesman, New York, N. Y., appeared as claimant in each of the libel proceedings. On December 5, 1947, upon motion of the claimant, the proceedings in the Eastern District of New York were removed for trial to the Southern District of New York.

On August 12, 1949, the claimant having failed to file an answer to the libels, judgments of condemnation were entered and the court ordered that the product be destroyed.

## VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

15198. Action for declaratory judgment. Cook Chocolate Company v. Watson B. Miller, Federal Security Administrator, and Tom C. Clark, Attorney General. Action against Attorney General dismissed. Oscar R. Ewing substituted as defendant. Tried to the Court. Complaint dismissed. Motion for new trial denied.

On or about February 17, 1947, the Cook Chocolate Company, Chicago, Ill., filed a complaint in the United States District Court for the District of Columbia, for the purpose of having the court determine (1) that the Federal Security Administrator should hold a public hearing as provided in Section 701 (e) of the Act, upon plaintiff's application to amend the cacao products regulations, and (2) that plaintiff's product, Vita Sert, did not violate the cacao products regulations established by the Federal Security Administrator. A motion to dismiss the complaint was filed thereafter on behalf of the defendants, and after consideration of the arguments and briefs of counsel, the following opinion was handed down on July 7, 1947:

BAILEY, *Justice*: "Section 371 (e) of the Federal Food, Drug and Cosmetic Act provides that the Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof *stating reasonable grounds therefor*, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by certain sections of the Act. The act further provides that after the public hearing the industry seeking a change in the regulation may appeal to the Court of Appeals from any order made by the Administrator based upon the evidence given at the public hearing.

"In this case the plaintiff, who is a large manufacturer of sweet chocolates, has sought to have the Administrator have a public hearing to amend his regulation upon sweet chocolates so that certain vitamins may be added to the chocolates. The plaintiff manufacturing a sweet chocolate to which certain vitamins have been added, the whole being sold under the name of Vita Sert, stated in his application certain facts in support of his application that the Administrator had permitted vitamins to be added to certain cereals providing optional standards for vitamin enrichment in Farina, macaroni, wheat, flour, and corn meal; that the British Ministry of Food announced that chocolate had been found to be the best medium for administering vitamin concentrates; that the United States Army had ordered and utilized vitaminized chocolate on a large scale in its emergency ration; that the Red Cross had also used large quantities of it for undernourished persons abroad, and annexed to its application letters from eminent physicians and other authorities.

"The Administrator refused to hold a public hearing, saying that no reasonable ground was shown for holding it. Thereupon, plaintiff brought this suit,

seeking a declaratory judgment, and to direct the Administrator to hold a public hearing upon plaintiff's application, and that the court determine that the plaintiff's product Vita Sert does not violate the Cacao products regulation established by the Federal Security Administrator.

"The defendant, the Federal Security Administrator, has moved to dismiss the complaint on the ground that the court is without jurisdiction and that the complaint fails to state facts sufficient to constitute a cause of action. As to the question of jurisdiction he contends that the action of the Administrator is a discretionary one and that the court has no power to review it. However, if the foregoing allegations of the petition filed with the Administrator are true, the action of the latter is clearly arbitrary. His power to fix regulations is given whenever 'in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers' and his holding that the plaintiff's application did not show reasonable grounds was not based upon this power but apparently upon some general authority not vested in him by the statute to define whether or not the addition of vitamins to chocolates to be used as a confection would be used by the public in sufficient quantities to justify a new regulation or an amendment to the existing regulation. See *Perkins v. Ely*, 307 U. S. 325.

"So far then, as the action of the Administrator in denying plaintiff's application is concerned, the motion to dismiss the complaint will be overruled.

"As to plaintiff's right to declaratory judgment as to whether or not its product Vita Sert is barred by the defendant's regulation, this question is governed by the case of *Helco Products Co., Inc. v. McNutt*, 78 App. D. C. 71. As to that and also as to the defendant, the Attorney General, the motion to dismiss will be sustained."

On August 19, 1947, an order was entered by the court, dismissing the plaintiff's cause of action for declaratory judgment to determine that the product Vita Sert does not violate the definition and standard of identity for cacao products, and dismissing the action as to the Attorney General. The court, however, denied the defendant's motion to dismiss the action for a declaratory judgment to determine that the Federal Security Administrator should hold a public hearing upon the plaintiff's application to amend the definition and standard of identity for cacao products; and on March 28, 1949, the matter was tried to the court. At the conclusion of the testimony, counsel for the defendant moved for judgment of dismissal on the merits. The court, after considering the evidence and arguments and briefs of counsel, handed down the following findings of fact and conclusions of law, sustaining the defendant's motion:

LETTS, Justice: "The above-entitled action came on for trial before the Court without a jury on the 28th day of March 1949. At the conclusion of the testimony adduced and presented by and on behalf of plaintiff, counsel for defendant moved for judgment of dismissal on the merits.

"The Court having heard and considered said testimony, the arguments of counsel and the briefs filed in support of and against said motion, and being duly advised in the premises, now makes the following Findings of Fact and Conclusions of Law:

#### FINDINGS OF FACT

"1. The plaintiff manufactures a sweet chocolate bar with added vitamins known as 'Vita Sert.'

"2. The Administrator of the Federal Security Agency promulgated a regulation under Section 401 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 341) fixing and establishing a definition and standard of identity for sweet chocolate, effective October 1, 1945. Such regulation does not provide for the addition of vitamins as an optional ingredient in sweet chocolate.

"3. On September 5, 1945, the plaintiff filed an application with the Administrator requesting that a public hearing be called under the provisions of Section 701 (e) of the Act (21 U. S. C. 371 (e)) to consider a proposal to amend the definition and standard of identity for sweet chocolate so as to permit the addition of vitamins as an optional ingredient. Plaintiff's application set forth the claims and representations made by the plaintiff as a basis for its request.

"4. The Administrator denied plaintiff's application in a letter to plaintiff dated October 11, 1945, on the ground that the application did not present reasonable grounds for concluding that the proposed amendment would promote honesty and fair dealing in the interest of the consumer.

"5. Upon receipt of the denial of the application, plaintiff, on July 24, 1946, filed a second application with the Administrator requesting that a public hearing be called to consider its proposal to amend the regulations so as to include vitamins as an optional ingredient in sweet chocolate. Plaintiff's second application set forth the claims and representations made by the plaintiff as a basis for such request.

"6. The Administrator denied plaintiff's second application in a letter to plaintiff dated January 15, 1947, on the ground that the application did not state reasonable grounds for the holding of a public hearing.

"7. No competent evidence was produced at the trial to prove or tending to prove the claims and representations contained in plaintiff's applications filed with the Administrator.

#### CONCLUSIONS OF LAW

"1. The only issue in this case is whether the Administrator abused his discretion or acted arbitrarily or illegally in denying plaintiff's applications.

"2. The burden of proof was upon the plaintiff to establish that the Administrator's action was arbitrary or illegal or an abuse of discretion.

"3. The applications and other documentary evidence admitted at the trial are only competent to show the claims and representations made by plaintiff to the Administrator and may not be accepted as proof of the facts therein set forth. The plaintiff's case rested on claims made to the Administrator which had not been established by any competent or relevant evidence.

"4. There is no competent evidence to prove or tending to prove that the Administrator acted arbitrarily or illegally or that he abused his discretion in denying plaintiff's applications.

"5. Upon the facts and the law the plaintiff has shown no right to relief.

"6. The defendant is entitled to an order and judgment for the dismissal of this action upon the merits, and for costs."

In accordance with the above findings of fact and conclusions of law, the action was ordered dismissed upon its merits. A motion for a new trial was made on behalf of the plaintiff, and on May 26, 1949, an order was entered denying such motion.

**15199. Misbranding of Raymond K. Auville's Ultra Natural Health Food Combination No. 4. U. S. v. 3 Cartons \* \* \*. (F. D. C. No. 23902. Sample No. 6204-K.)**

**LIBEL FILED:** November 7, 1947, Western District of Pennsylvania.

**ALLEGED SHIPMENT:** During July 1947, by Raymond K. Auville, from Kerens, W. Va.

**PRODUCT:** 3 3-ounce cartons of Raymond K. Auville's Ultra Natural Health Food Combination No. 4 at South Heights, Pa.

**LABEL, IN PART:** "Raymond K. Auville's Ultra Natural Health Food Combination No. 4—New Formula \* \* \*. Contents: Approximate measurement of ingredients; wild cherry leaves, three parts; wild Indian heart leaves, one part; walnut leaves, one part; wild cherry bark, two parts; may apple root, one part; red root, one half one part; red root, trace; vine fern, one half one part; alum root, one half one part; prickly ash bark, trace."

**NATURE OF CHARGE:** Misbranding, Section 403 (a), the label statements "Health Food \* \* \* Natural Health Food \* \* \* nutritional aid for the naturalization of the blood stream" were false and misleading since the article would not maintain health in those who are healthy or restore health to those who are unhealthy, and it would not make natural the blood stream.